IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, and WISCONSIN ALUMNI RESEARCH FOUNDATION	)	
Plaintiffs,	)	Case No. 08-CV-6659
v.	)	Judge Kocoras
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.	)	Magistrate Judge Keys
Defendants.	)	

PLAINTIFFS' MOTION TO COMPEL
PRODUCTION OF DOCUMENTS AND WITNESSES

Plaintiffs Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF") respectfully move, pursuant to Rule 37 of the Federal Rules of Civil Procedure, for an order compelling defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") to provide discovery related to evidence of long-felt need, unpredictability in the art, copying, and the failure of others—important indicium of the nonobviousness of the inventions of the patents-in-suit. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *KSR Int'l Co. v Teleflex Inc.*, 550 U.S. 398, 406, 416-18 (2007).

I. Background

This is a suit for patent infringement under the Hatch-Waxman Act, 21 U.S.C. § 355(j), and the United States Patent Laws, including 35 U.S.C. § 271(e)(2). The action involves two patents. The first patent, U.S. Patent No. 5,587,497 (the "'497 patent"), concerns the compound paricalcitol, a Vitamin D analog that is the active ingredient in Abbott's pharmaceutical product,

Zemplar®. The second patent, U.S. Patent No. 5,246,925 (the "'925 patent"), concerns a method for the treatment of secondary hyperparathyroidism—a serious bone-related disorder—in patients with chronic kidney disease with paricalcitol. In August 2008, Teva filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to manufacture, use and sell its generic version of Zemplar®. The ANDA included a Paragraph IV certification that Plaintiffs' '497 and '925 patents are invalid, unenforceable, or not infringed. As Teva's filing of the ANDA constituted an act of infringement under 35 U.S.C. §271(e)(2), Plaintiffs sued Defendants in this Court for infringing the '497 and '925 patents. One of Teva's primary defenses in this case is that the patents are allegedly "obvious" under 35 U.S.C. § 103.

Abbott markets Zemplar® in the United States for treatment of patients suffering from secondary hyperparathyroidism resulting from chronic kidney disease (CKD).[1] Notably, when Zemplar® was first approved for marketing in the United States in 1998, it quickly became the standard of care for treatment of that disease. Today, more than 12 years after its first approval, Zemplar® remains the standard of care for the treatment of patients suffering from advanced renal disease, no doubt explaining why Teva desires to sell a generic knock-off.

Prior to the inventions of the patents-in-suit, researchers in the field, *including scientists at Teva*, recognized the need for improved therapies for the treatment of secondary

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[1] CKD leads to a disruption of the body's ability to regulate blood levels of Vitamin D, calcium, phosphorus, and parathyroid hormone (PTH) and results in significant complications including secondary hyperparathyroidism. Traditional treatments for secondary hyperparathyroidism included calcitriol (innovated by Plaintiffs and copied and currently sold by Teva), the active form of Vitamin D_3. Like Zemplar, the administration of calcitriol effectively lowers levels of PTH. However, administration of calcitriol results in undesirable patient side effects including increased levels of blood calcium (hypercalcemia) and phosphorus (hyperphosphatemia).

hyperparathyroidism. For example, Teva's U.S. Patent No. 4,997,824 (the "'824 patent"), filed in 1987, explained:

> The use of [calcitriol] is now established in the treatment of renal bone diseases. Its administration increases calcium absorption from the gut and consequently, plasma calcium, and suppresses secondary hyperparathyroidism and its skeletal consequences. . . . *This therapeutic effect is also the major cause of vitamin D toxicity, namely hypercalcemia. Its use is therefore contraindicated and indeed of limited value* in patients with preexisting hypercalcemia due to aluminum toxicity or tertiary hyperparathyroidism.

(Ex. A, col. 1, ll. 44-58 (emphasis added).)

Based on publically available information, it appears that, during the 1970s and 1980s, Teva engaged in research and development efforts in an attempt to identify improved therapies in the field. In particular, Teva appears to have investigated the use of Vitamin D "analogs"—compounds that are structurally modified from naturally-occurring forms of Vitamin D. (*See, e.g.,* '824 patent, col. 1, lines 8-12) ("[T]he invention provides a method and composition for the treatment of renal osteodystrophy diseases in humans comprising the administration to a patient of 6-40 micrograms per day of 24,25-dihydroxycholecalciferol [a vitamin D_3 analog] . . . ."). Despite its efforts, Teva's research failed to result in a successful Vitamin D analog that was approved by the FDA for use in the United States.

During the same time period, Dr. Hector DeLuca and his team of researchers at the University of Wisconsin were also investigating Vitamin D analogs. Dr. DeLuca's laboratory discovered that seemingly minor structural modifications of Vitamin D analogs resulted in unpredictable and surprising effects on biological activity. The '497 and '925 patents-in-suit were filed in 1989 based on the discovery that a particular Vitamin D analog, paricalcitol (Zemplar®), exhibited unexpected and surprising properties. Unlike other compounds such as

calcitriol, administration of paricalcitol effectively lowers PTH levels without resulting in a significant increase in blood calcium or phosphorus levels. (*E.g.,* '497 patent, col. 6, l. 35-col. 8, l. 3.) Thus, the discovery of paricalcitol was a solution to a problem that had plagued researchers in the field for years.

Nevertheless, despite the failures of Teva and others to come up with a satisfactory drug prior to paricalcitol, Teva contends, in hindsight, that the patents covering paracalcitol and its use are invalid because they were obvious all along. But in order to guard against such hindsight attacks, the Supreme Court has emphasized the importance of "objective" considerations of nonobviousness, including long-felt need, unpredictability in the art, and the failure of others. *Graham*, 383 U.S. at 17-18; *KSR Int'l Co.*, 550 U.S. at 406, 416-18. While sometimes referred to in shorthand as "secondary factors" of nonobviousness, the Federal Circuit has emphasized that such evidence is *always* to be considered, and is often the most probative and cogent evidence of nonobviousness in the record. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006). Thus, there can be no legitimate dispute that the requested discovery (regarding Teva's failed research and development efforts in attempting to overcome the same deficiencies in treating patients with CKD faced by the inventors of the patents-in-suit) is materially relevant in this case.

II. Teva Refuses to Produce Any Materials or Witnesses

Teva has refused to produce documents concerning any Vitamin D analog (other than paricalcitol) in response to Plaintiffs' Requests for Production Nos. 42, 43, 45, and 46, served four months ago on September 15, 2009:

> REQUEST FOR PRODUCTION NO. 42
> All documents concerning Teva's research and development, formulation,

> testing (including clinical trials), analyses, or studies of Vitamin D and its analogs, metabolites, and other related compounds – including but not limited to the compounds described and/or claimed in Teva's U.S. Patents Nos. 4,758,382 and 4,997,824 – and such documents to include but not limited to invention disclosures, notebooks, correspondence, investigations, summaries, meeting notes or minutes, reports, presentations, sketches, evaluations, analyses, test data, descriptions of tests or studies, analytical data, and results or conclusions reached from such research, tests, analyses, or studies.
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> REQUEST FOR PRODUCTION NO. 43
> All documents concerning Teva's efforts to sell, license, or otherwise commercially develop any compounds related to Vitamin D and its analogs, metabolites, and other related compounds – including but not limited to the compounds described and/or claimed in Teva's U.S. Patents Nos. 4,758,382 and 4,997,824.
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> REQUEST FOR PRODUCTION NO. 45
> All documents relating to the use of 24,25-dihydroxycholecalciferol as a treatment for renal osteodystrophy and/or other renal bone disease.
>
> REQUEST FOR PRODUCTION NO. 46
> All documents relating to Teva's efforts to develop 24,25-dihydroxycholecalciferol as a treatment for renal osteodystrophy and/or other renal bone disease.

(*See* Ex. B.)

Teva has itself served numerous document requests seeking production of documents related to any Vitamin D analog, metabolite or other related compound. As described in more detail below, in view of the potentially large number of documents responsive to the parties' respective discovery requests on these topics, Plaintiffs proposed that the parties seek a compromise that would result in the production of relevant documents without undue burden. Plaintiffs also agreed to produce a witness in response to Topic 14 in Teva's 30(b)(6) notice to testify "about the factual bases for the past and continuing research and development efforts concerning synthetic Vitamin D analogs that have been modified to differ from naturally-occurring forms of Vitamin D." (Ex. C)

In contrast to Plaintiffs, Teva has refused to produce a witness to testify on the full scope of Topic 6 in Plaintiffs' 30(b)(6) notice, served on November 27, 2009. Topic 6 seeks information concerning Teva's "past and continuing research and development efforts, both successful and unsuccessful, related to all its paricalcitol products, Vitamin D analogs" and related compounds. (*See* Ex. D.) Teva objected to this Topic as "not reasonably calculated to lead to the discovery of admissible evidence because it seeks information regarding products that are not the subject of ANDA No. 90-829, are not paricalcitol, and are not subject to the patents in suit here." (*Id.*)

Finally, on December 23, 2009, Plaintiffs served deposition notices for Messrs. Mordecai Popovtzer and Ben Weiner, two of the named inventors on Teva's patents related to the research and development of Vitamin D analogs for the treatment of renal diseases caused by chronic kidney disease. (*See* Exs. E, F.) Teva has similarly refused to provide these individuals for their depositions. (*See* Ex. G, Letter from A. Hassett to R. Shaffer, Dec. 30, 2009, at 2.)

III. Teva Rejected Plaintiffs' Offer to Narrowly Focus the Requested Discovery

After serving its discovery requests in September, Plaintiffs have worked to resolve this issue without Court intervention.[2] In compliance with Local Rule 37.2, counsel have conferred by teleconference on December 4, 2009, and January 6, 2010 and in writing on November 23, 2009, December 9, 29, and 30, 2009, and January 7 and 12, 2010, and have attempted in good faith to resolve the issues raised by this motion. The parties, however, were unable to reach a resolution. For example, during a December 4, 2009, telephone conference, Plaintiffs proposed a compromise to Teva's counsel, whereby both parties would limit their respective requests for discovery on Vitamin D analogs (other than paricalcitol) by agreeing to produce a ***focused,***

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[2] Abbott replaced its former lead counsel (Patterson Belknap) with the undersigned counsel (Finnegan) in late October 2009.

representative sample of documents concerning past and continuing research and development of Vitamin D analogs that have been modified to differ from naturally-occurring forms of Vitamin D. Alternatively, Plaintiffs proposed that the parties take respective Rule 30(b)(6) depositions on this narrowed topic followed by tailored requests for specific documents.

Not until December 30, 2009, did Defendants finally refuse Plaintiffs' compromise, proposing instead that "each side withdraw its requests for this type of discovery" or "stipulate to a number of high-level facts that relate to its non-paricalcitol Vitamin D analogue research and development." (Ex. G, Letter from A. Hassett to R. Shaffer, Dec. 30, 2009, at 2.) During a meet and confer on January 6, 2010, Defendants once again refused to produce the relevant discovery and unilaterally sought to end the discovery dispute by stipulating to "high level facts." (Letter from A. Hassett to R. Shaffer, Jan. 7, 2009.) After considering Teva's proposal, Plaintiffs informed Teva that they would not forego this discovery, which is highly-relevant to the nonobviousness of the patents-in-suit.

Teva's proposed fact stipulation confirmed Plaintiffs' suspicions that Teva tried, but failed, to develop a suitable Vitamin D analog and that Teva may have copied a critical chemical characteristic of paricalcitol in its later efforts to create new analogs outside of its program to make a generic form of the drug. Teva's proposed fact stipulation also brought to light that Teva conducted relevant research that is not otherwise publically available. Plaintiffs should be allowed to explore whether Teva tried and failed to discover a Vitamin D analog effective for the treatment of secondary hyperparathyroidism and to obtain any evidence of long-felt need, copying, and unpredictability in the field of Vitamin D analogs that may be shown by Teva's research and development efforts. Such discovery would not unduly burden Teva because it would require production of only a limited number of documents; would not result in any

witnesses being deposed for a second time; and would not impact the close of fact discovery on other issues.

Defendants' refusal to produce documents, a Rule 30(b)(6) witness, and its inventors on its own research and development efforts on Vitamin D analogs—plainly relevant to this litigation—prejudices Plaintiffs. Under controlling Supreme Court and Federal Circuit law, Teva's past and continuing research and development efforts related to Vitamin D analogs, including compounds other than paricalcitol, is likely to constitute evidence of long-felt but unresolved need, unpredictability in the art, copying, failure of others, and the unexpected properties of paricalcitol as compared to other Vitamin D analogs—all secondary indicia of nonobviousness that must be considered by this Court in assessing the validity of the patents-in-suit. *See, e.g.*, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) ("Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results *must* be considered *before* a conclusion on obviousness is reached . . . .") (emphasis added); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985) ("[I]t is legal error for a district court to fail to consider relevant evidence going to secondary considerations"); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000) ("The district court erred in failing to consider, or at least discuss, evidence of secondary considerations."). Moreover, these "secondary considerations [are also relevant] in connection with the refutation of prima facie demonstrations of obviousness in the double patenting context." *In re Glaxo Patent Litigation*, 450 F. Supp. 2d 435, 437 (S.D.N.Y. 2006); s*ee also Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F. Supp. 2d 820, 911 (S.D. Ind. 2005).[3] Thus,

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[3] Defendants have asserted affirmative defenses of invalidity of the '497 and '925 patents. (*E.g.,* Teva Pharmaceuticals USA, Inc.'s Answer, D.I. 23.) In particular, Defendants contend

Defendants' assertions that Plaintiffs' requested discovery is not relevant, or is not reasonably calculated to lead to the discovery of admissible evidence, are without merit.

IV. Conclusion

For the foregoing reasons, Plaintiffs respectfully request an order requiring Teva to: (1) produce a representative sample of documents concerning its past and continuing Vitamin D research and development efforts sufficient to show the scope of that research, the modified Vitamin D compounds they were testing, and the reasons for any decision to pursue or not pursue clinical and commercial development of such compounds; (2) provide a witness to testify on the full scope of Topic 6 in Plaintiffs' 30(b)(6) notice; and (3) provide deposition dates for Messrs. Ben Weiner and Mordecai Popovtzer.

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that the patents-in-suit are invalid as obvious over prior art under 35 U.S.C. § 103 and invalid under the judicially created doctrine of obviousness-type double patenting.

Dated: January 15, 2010

Respectfully submitted,

ABBOTT LABORATORIES and WISCONSIN ALUMNI RESEARCH FOUNDATION

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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2010, a copy of the foregoing Plaintiffs' Motion to Compel Production of Documents and Witnesses was filed electronically. Notice of this filing will be sent to the following by operation of the Court's electronic filing system.

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